

SEP 3 1996

510 (k) SUMMARY**I. ADMINISTRATIVE**

Submitter: Maxxim Medical, Inc.
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Contact Person: Ernest J. Henley

Date of Preparation: July 3, 1996

II. DEVICE NAME

Proprietary Name: Dermaplex Hydrogel Wound Dressing

Common Name: Wound Dressing

Classification Name: Hydrogel wound and burn dressing

III. PREDICATE DEVICE

MPM GelPad (Hydrogel Saturated Sterile Gauze); MPM Medical, Inc.; K933495.

IV. DEVICE DESCRIPTION

The Dermaplex Hydrogel Wound Dressing consists of a 12-ply cotton gauze pad dressing impregnated with a clear, viscous hydrogel. The product is available in four sizes (2" x 2", 4" x 4", 4" x 8" and 6" x 10") and is supplied sterile in sealed aluminum/plastic laminate pouches.

Biocompatibility of the device has been established by a primary dermal irritation test in rabbits and a sensitization test in guinea pigs. The product meets the requirements of the USP Cytotoxicity Test (Agarose Diffusion).

V. INTENDED USE

For the local management of pressure ulcers, stasis ulcers, 1st and 2nd degree burns, and full and partial thickness wounds.

VI. COMPARISON TO PREDICATE DEVICE

The Dermaplex Hydrogel Wound Dressing is similar in composition, function and intended use to the MPM GelPad (MPM Medical, Inc., K933495) and other wound dressing products consisting of a cotton pad saturated with hydrogel.

Accordingly, Maxxim Medical, Inc. concluded that the Dermaplex Hydrogel Wound Dressing is as safe and effective for its intended use and performs at least as well as legally marketed predicate devices, such as the MPM GelPad.